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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,358	10/16/2001	Rembert Pieper	42521	3368

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EXAMINER
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VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/977,358	PIEPER ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on March 7, 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 32,52,62-69,84,85,88,89,104-107 and 110-113 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32,52,62-69,84,85,88,89,104-107 and 110-113 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1641

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

Applicants file a SECOND request for continued examination under 37 CFR 1.114 after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action is withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 17, 2007, is entered.

Art Unit: 1641

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32, 52, 62-69, 84-85, 88-89, 104-107 and 110-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 63 and 84, the recitation of "specific predefined proteins" is indefinite. The identity of objects and/or steps required for "predefining" proteins is not clear.

In claim 63, the following type mismatches are indefinite: (paraphrasing mine)

- (a) "first protein present in the sample binds[...] such that first and second proteins are removed"
- (b) "second protein present in the sample binds[...] such that first and second proteins are removed"
- (c) "first protein present in the sample binds[...] and second protein present in the sample binds[...] such that first and second proteins are removed"

Whether/how the object(s) and/or step(s) required for performing "binding" are coextensive with, or amount(s) to, the object(s) and/or step(s) required for performing "removing" is not clear.

In claim 84, the type mismatch "ligands become bound[...] and thereby removed" is indefinite. Whether/how the object(s) and/or step(s) required for performing "binding" are coextensive with, or amount(s) to, the object(s) and/or step(s) required for performing "removing" is not clear.

Art Unit: 1641

In claim 63, the recitation of "each solid phase matrix comprises a plurality of particles" is indefinite, wherein "each solid phase matrix" = a bead (see specification p. 9, lines 10-11, "[a] suitable matrix is, for example a bead or a microbead shape") (emphases added). Whether/how a bead comprises "a plurality of particles" is not clear.<sup>1</sup>

In claim 84, the recitation of "each solid phase matrix comprises a plurality of particles" is indefinite, wherein "each solid phase matrix" = a bead (see specification p. 9, lines 10-11, "[a] suitable matrix is, for example a bead or a microbead shape") (emphases added). Whether/how a bead comprises "a plurality of particles" is not clear.<sup>2</sup>

In claim 63, the recitation of "a first and second solid phase matrix contacting each other" is indefinite, wherein "each solid phase matrix" = beads (see specification p. 13, lines 4-7, "the matrix is loose beads... matrix beads") (emphases added). Whether/how a matrix of beads is in contact with another matrix of beads is not clear. Whether the claim limitation "contacting" requires a matrix of beads to be stacked, layered and/or adjoined on/to another matrix of beads is not clear. How a matrix of beads that is stacked, layered and/or adjoined on/to another matrix of beads can be "present as a mixture" is not clear.<sup>3,4</sup>

In claim 84, the recitation of "each solid phase matrix is in contact with at least one other solid phase matrix" is indefinite, wherein "each solid phase matrix" = beads (see specification p. 13, lines 4-7, "the matrix is loose beads... matrix beads") (emphases added). Whether/how a matrix of beads is in contact with another matrix of beads is not clear. Whether the claim limitation "in contact" requires a matrix of

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<sup>1</sup> Applicants may obviate this rejection by amending the affected phrase as follows: a first and a second solid phase matrix contacting each other, wherein each solid phase matrix comprises a plurality of particles particle, and wherein the particles of the first and second solid phase matrices are present as a mixture in said affinity binding composition;

<sup>2</sup> Applicants may obviate this rejection by amending the affected phrase as follows: a plurality of solid phase matrices arranged such that each solid phase matrix is in contact with at least one other solid phase matrix; and... wherein each solid phase matrix comprises a plurality of particles particle, and wherein the particles are present in the affinity binding composition as a mixture;

<sup>3</sup> Applicants may obviate this rejection by amending the affected phrase as follows: a first and a second solid phase matrix contacting each other, wherein each solid phase matrix comprises a plurality of particles, and wherein the particles of the first and second solid phase matrices are present as a mixture in said affinity binding composition;

<sup>4</sup> Alternatively, Applicants might obviate this rejection by amending the affected phrase as follows: a solid mixture of a first particle type and a second particle type solid phase matrix contacting each other, wherein each solid phase matrix comprises a plurality of particles, and wherein the particles of the first and second solid phase matrices are present as a mixture in said affinity binding composition.

Art Unit: 1641

beads to be stacked, layered and/or adjoined on/to another matrix of beads is not clear. How a matrix of beads that is stacked, layered and/or adjoined on/to another matrix of beads can be present "as a mixture" is not clear.<sup>5,6</sup>

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<sup>5</sup> Applicants may obviate this rejection by amending the affected phrase as follows: a plurality of solid phase matrices arranged such that each solid phase matrix is in contact with at least one other solid phase matrix; and... wherein each solid phase matrix comprises a plurality of particles, ~~and wherein the particles are present in the affinity binding composition as a mixture;~~

<sup>6</sup> See *supra*, note 4.

Art Unit: 1641

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 52, 62-69, 89, 104, 110 and 112 are rejected under 35 U.S.C. 102(b) as being anticipated by Stausbøl-Grøn *et al.*, 391 FEBS LETTERS 71 (1996).

Stausbøl-Grøn *et al.* describe a method for separating proteins (see p. 71, right column, last paragraph, second sentence, "single-chain Fv antibody fragments (scFv)"; see also Section 1 *Introduction*, first sentence, "coat protein") from a sample (see Section 2.4 *Competitive two solid phase biopanning-protein mixture*, second paragraph, "[a]n aliquot of  $10^{12}$  colony-forming units (cfu) from the naïve library, and competitive soluble MIX protein"; see also Section 2.5 *Competitive two solid phase biopanning-cytosolic cell extract from a melanoma cell line*, fourth sentence, "naïve library ( $10^{12}$  cfu) and competitive soluble FM55p proteins") that contains proteins and recovering a modified sample (see Abstract, "enrich selectively phage displayed antibodies directed against proteins constituting a difference between two populations of cells") comprising the steps of:

- (1) removing (see p. 72, col. 1, fifth paragraph, "immunobead was washed") at least two specific predefined proteins (see p. 73, col. 2, second paragraph, "Competitive proteins", see Fig. 2(A), MIX+LDH versus MIX; see also Section 3 *Results and discussion*, p. 74, right column,

Art Unit: 1641

second full paragraph, first sentence, "selection inhibition of all similarities"; see *also* last sentence, "as many proteins as possible") (emphasizing plurality of proteins) from a sample that contains the at least two specific predefined proteins, thereby

- (2) recovering the modified sample containing a plurality of proteins that was present in the sample (see Abstract, "enrich selectively phage displayed antibodies directed against proteins constituting a difference between two populations of cells") prior to removal of the at least two specific predefined proteins;

wherein:

- (a) the predefined ligands are proteins (see p. 73, col. 2, second paragraph, "Competitive proteins", see Fig. 2(A), MIX+LDH versus MIX; see *also* Section 3 *Results and discussion*, p. 74, right column, second full paragraph, last sentence, "as many proteins as possible"); and
- (b) the removing step comprises contacting the sample with an affinity binding composition (see Fig. 1, "two solid phase system") comprising:
- i. a first and second solid phase matrix (see Fig. 1, "two solid phase system") contacting each other (see Fig. 1, "immunobeads in an immunotube"), wherein each solid phase matrix comprises a plurality of particles (see Fig. 1, "immunobeads in an immunotube"), wherein the particles are present in a mixture (see p. 72, col. 1, sixth paragraph, "4 ml 2% MPBS... five immunobeads... were added");

Art Unit: 1641

- ii. a first receptor (see Fig. 1, "LDH") immobilized on said first solid phase matrix (see Fig. 1, "immunobeads"); and
- iii. a second receptor (see Fig. 1, "MIX proteins") immobilized on said second solid phase matrix (see Fig. 1, "immunotube").

With respect to claims 64-69, Stausbøl-Grøn *et al.* describe a method wherein "different coating conditions in parallel" is performed "to cover as many proteins as possible" (see p. 74, col. 2, second full paragraph, last sentence).

Art Unit: 1641

Claims 32, 52, 62, 84, 89, 104, 111 and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by Stausbøl-Grøn *et al.*, 391 FEBS LETTERS 71 (1996).

Stausbøl-Grøn *et al.* describe a method for separating (see Abstract, first sentence "enrich selectively"; see also Abstract, second sentence, "isolated"; see also Fig. 1, bottom, "rescued"; see also Section 3 *Results and discussion*, p. 73, right column, first paragraph, second sentence, "obtain"; see also Section 3 *Results and discussion*, p. 73, right column, third paragraph, first sentence, "enrich preferentially"; see also Section 3 *Results and discussion*, p. 74, right column, second full paragraph, first sentence, "selection") proteins (see p. 71, right column, last paragraph, second sentence, "single-chain Fv antibody fragments (scFv)"; see also Section 1 *Introduction*, first sentence, "coat protein") from a sample (see p. 71, right column, last paragraph, second sentence, "naïve phagemid library") that contains proteins and recovering a modified sample comprising the steps of:

- (1) removing at least two specific predefined proteins (see Section 3 *Results and discussion*, p. 74, right column, second full paragraph, first sentence, "selection inhibition of all similarities"; see also last sentence, "as many proteins as possible") (emphasizing plurality of proteins) from a sample, thereby
- (2) producing and/or recovering the modified sample (see Abstract, first sentence "enrich selectively phage displayed antibodies directed against proteins constituting a difference between two populations of cells"; see also Abstract, second sentence, "[a]ntibodies recognizing a defined difference between two otherwise identical protein mixtures were isolated"; see also Fig. 1, bottom, "phage bound to the target proteins on the immunobead(s) were rescued"; see also Section 3 *Results and discussion*, p. 73, right column, first paragraph, second sentence, "[t]he goal is to establish a competitive panning procedure, which can be used to obtain phage antibodies against antigens expressed differentially in different cell populations"; see also Section 3 *Results and discussion*, p. 73, right column,

Art Unit: 1641

third paragraph, first sentence, "we were able to enrich preferentially for phage that were reactive against LDH"; see also Section 3 *Results and discussion*, p. 74, right column, second full paragraph, first sentence, "selection against all differences");

wherein:

- (a) the predefined ligands are proteins (see Section 3 *Results and discussion*, p. 74, right column, second full paragraph, last sentence, "as many proteins as possible"); and
- (b) the removing step comprises contacting (see p. 71, right column, last paragraph, second sentence, "biopanning procedure") the sample (see p. 71, right column, last paragraph, second sentence, "naïve phagemid library") with an affinity binding composition (see p. 71, right column, last paragraph, second sentence, "single-chain Fv antibody fragments (scFv)") comprising:
  - i. a plurality of solid phase matrices (see p. 71, right column, last paragraph, second sentence, "naïve phagemid library") (emphasis added) arranged such that each solid phase matrix is in contact with at least one other solid phase matrix (see p. 71, right column, last paragraph, second sentence, "naïve phagemid library") (emphasis added);
  - ii. a plurality of receptors having different protein binding specificities (see p. 71, right column, last paragraph, second sentence, "single-chain Fv antibody fragments (scFv)");

Art Unit: 1641

wherein the receptors (see p. 71, right column, last paragraph, second sentence, "single-chain Fv antibody fragments (scFv)") are immobilized on the plurality of solid phase matrices (see p. 71, right column, last paragraph, second sentence, "naïve phagemid library") such that each solid phase matrix has a different protein binding specificity (see p. 72, left column, Section 2.1 *Library and bacteria*, first sentence, " $10^8$  clones"),

wherein each solid phase matrix comprises a plurality of particles (see Section 1 *Introduction*, first sentence, "coat protein"), wherein the particles (see Section 1 *Introduction*, first sentence, "coat protein") are present in a mixture (see Fig. 1, "two solid phase system");

Art Unit: 1641

Claims 32, 52, 62-69, 84, 88-89, 104 and 110-113 are rejected under 35 U.S.C. 102(e) as being anticipated by Payan (US 6,455,263).

Payan describes a method for separating proteins (see col. 13, lines 1-2, "beads are then sorted using fluorescent-activated cell sorting") from a sample that contains proteins (see e.g., col. 3, lines 48-49, "library of candidate agents"; col. 14, lines 24-25, "third, fourth, etc. populations of target molecules") and recovering a modified sample (see col. 2, lines 64-65, "collected") comprising the steps:

- (1) removing at least two specific predefined proteins (see e.g., col. 13, lines 10-11, "non-fluorescent beads") from a sample that contains the at least two specific predefined proteins (see e.g., col. 3, lines 48-49, "library of candidate agents"; col. 14, lines 24-25, "third, fourth, etc. populations of target molecules"), thereby producing a modified sample containing a plurality of proteins (see col. 13, lines 10-11, "sorting results in a population of non-fluorescent beads and at least one population of fluorescent beads");
- (2) recovering the modified sample (see col. 2, lines 64-65, "collected");

wherein:

- (a) the predefined ligands are proteins (see Abstract, "peptides"); and
- (b) the removing step comprises contacting the sample with an affinity binding composition (see e.g., col. 3, lines 48-49, "library of candidate agents"; col. 14, lines 24-25, "third, fourth, etc. populations of target molecules") comprising:
  - i. a first and a second solid phase matrix contacting each other, wherein each solid phase matrix comprises a plurality of particles (see col. 7, line 52, "bead

Art Unit: 1641

composition"), and wherein the particles are present as a mixture (see col. 12, line 55, "reaction mixture").

With respect to claims 88 and 104, Payan describes antibody candidate agents (see col. 9, lines 39-42).

With respect to claim 89, Payan describes libraries of synthetic compounds and their generation (see col. 3, lines 51-65).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32, 52, 62-69, 84-85, 88-89, 104-107 and 110-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies (US 6,696,304) in view of Payan (US 6,455,263).

Davies describes a method for separating proteins (see col. 16, line 67, "screening of combinatorial libraries") comprising the step of:

- (1) contacting a sample with an affinity binding composition (see col. 9, lines 48-50, "[a] test analyte/microparticle complex is added directly to the mixture of microparticles with immobilized protein standards") comprising:

(a) a plurality of solid phase matrices (see Title, "particulate solid phase") arranged such that each solid phase matrix is in contact with at least one other solid phase matrix (see col. 9, lines 48-50, "[a] test analyte/microparticle complex is added directly to the mixture of microparticles with immobilized protein standards"), and wherein each solid phase matrix (see col. 9, line 48, "[a] test analyte/microparticle complex"; col. 9, lines 49-50, "mixture of microparticles with immobilized protein standards") comprises a plurality of particles, and wherein the pluralities of particles are present as a mixture (see col. 9, lines 48-49, "added directly to the mixture"); and

Art Unit: 1641

(b) a plurality of receptors immobilized on the plurality of solid phase matrices (see *e.g.*, col. 14, line 52, "antibody").

Davies does not describe the steps of "removing at least two specific predefined proteins from a sample", "producing a modified sample" and "recovering the modified sample".

However, Payan describes a method for separating proteins (see col. 13; lines 1-2, "beads are then sorted using fluorescent-activated cell sorting") and recovering a modified sample (see col. 2, lines 64-65, "collected") comprising the steps:

(2) removing at least two specific predefined proteins (see *e.g.*, col. 13, lines 10-11, "non-fluorescent beads") from a sample that contains the at least two specific predefined proteins (see *e.g.*, col. 3, lines 48-49, "library of candidate agents"; col. 14, lines 24-25, "third, fourth, etc. populations of target molecules"), thereby producing a modified sample containing a plurality of proteins (see col. 13, lines 10-11, "sorting results in a population of non-fluorescent beads and at least one population of fluorescent beads"); and

(3) recovering the modified sample (see col. 2, lines 64-65, "collected").

It would have been obvious for a person of ordinary skill in the art to perform the method for screening combinatorial libraries of Davies with the added procedural steps of producing and recovering a modified sample because Payan discovered that producing and recovering a modified sample using FACS allows for subsequent analysis (see col. 2, line 65), treatment (see col. 3, line 8) and/or characterization (see col. 3, line 10) of separated proteins.

With respect to claim 85, Davies describes an affinity purification column containing the affinity binding composition (see col. 17, lines 47-48, "affinity purification columns").

Art Unit: 1641

With respect to claims 104-107, Davies describes an affinity binding composition that binds to albumin (see col. 15, line 9), immunoglobulins (see col. 15, lines 16-19), transferrin (see col. 15, line 16), haptoglobin (see col. 15, line 15), alpha-1-antitrypsin (see col. 15, line 12), alpha-2-macroglobulin (see col. 15, line 12), alpha-1-acid glycoprotein (see col. 15, line 9), hemopexin (see col. 15, line 15), transthyretin (see col. 15, line 14), apolipoprotein A1 (see col. 15, line 13) and prealbumin (see col. 15, line 14).

Art Unit: 1641

Claims 32, 52, 62-69, 84-85, 88-89, 104-107 and 110-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies (US 6,696,304) in view of Fulwyler *et al.* (US 3,710,933).

Davies describes a method for separating proteins as substantially described, *supra*, and incorporated herein.

Davies does not describe the steps of "removing at least two specific predefined proteins from a sample", "producing a modified sample" and "recovering the modified sample".

However, Fulwyler *et al.* describes a particle sorter (see Title) for sorting stuff.

It would have been obvious for a person of ordinary skill in the art to perform the method of Davies with a particle sorter because Fulwyler *et al.* describe their device as "rapid and automatic" (see col. 3, lines 59-61).

Art Unit: 1641

***Response to Arguments***

In prior Office Action, Examiner objected to the specification for failing to provide proper antecedent basis for the language "specific predefined proteins" as recited in claims 63 and 84. Applicants' indicated support for this claim language in paragraph [0030] of the specification (see Applicants' reply, p. 7 of 19, fifth paragraph) is sufficient to overcome this objection. Accordingly, this objection is withdrawn.

Examiner maintains all other rejections for reasons already of record.


***Conclusion***

No claims are allowable at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci  
Examiner  
Art Unit 1641

djv

  
LONG V. LE 03/29/07  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600